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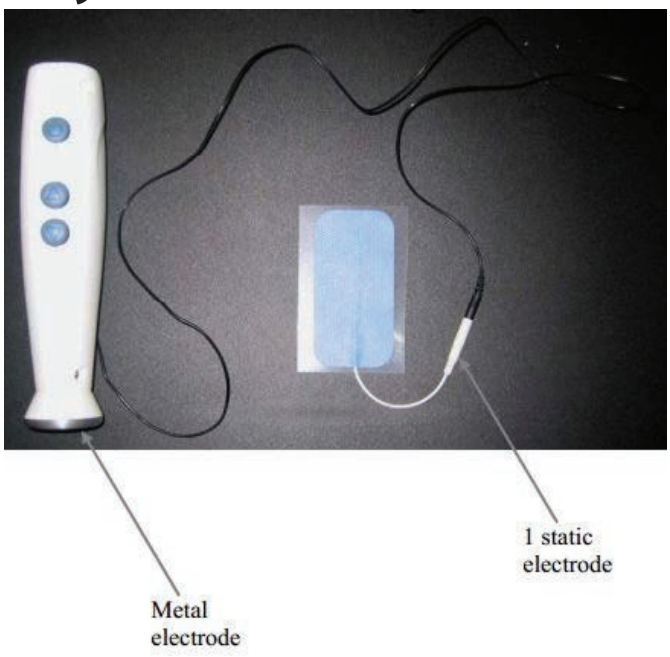
Life Lived Well

EP Global Communications, Inc.
EPGL Medical Sciences

MPD 1
Physician's User Manual



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Introduction

Thank you for purchasing the MPD 1 from EPGL Medical. The MPD 1 offer physicians a unique way to reach the deepest, most painful muscle trigger points your patients present with. If used properly as prescribed within this User Manual, the MPD 1 can be used in assistance of treatment for the most difficult to reach trigger points, making it one of the most useful new tools for physicians, unlike any other device available to physicians. MPD 1's patented, unique and powerful waveform make it possible for the device to send concentrated energy deeply into the muscles while maintaining safety on the surface of the skin. The MPD 1 is FDA 510k Cleared as safe for marketing and manufacturing.

The MPD 1 is a wireless wand device which offers two interchangeable heads for the treatment of various size sites. The interchangeable heads allow for treatment in larger areas. Its portability also allows for easy transportation of the unit without the need of bulky equipment and wires.

Product Contents

EPGL Medical recommends the use of supplied accessories, including electrodes, conductive gel, and lead wires.

Included with MPD 1 are the following:

- Two interchangeable aluminum electrode heads (1” and 1.5” diameters)
- Two self-adhesive electrodes (size 2” x 3.5”)
- Two standard 9V batteries

Safety

This device is not designed to be connected with any electrical equipment unless manufactured and approved by EPGL Medical. This device should not be exposed to water.

NOTE: This includes patient lead cords, batteries, and self-adhesive electrodes.

Device Features and Controls

MPD 1 is a user friendly device and uses only three buttons; a power button and two buttons to increase or decrease intensity. The top of the unit has a large easy to read liquid crystal display (LCD) which displays the intensity setting as well as any errors that may occur. The green LED indicates the unit is on and the red LED (low battery) indicates the battery needs to be replaced. See Figure 1.

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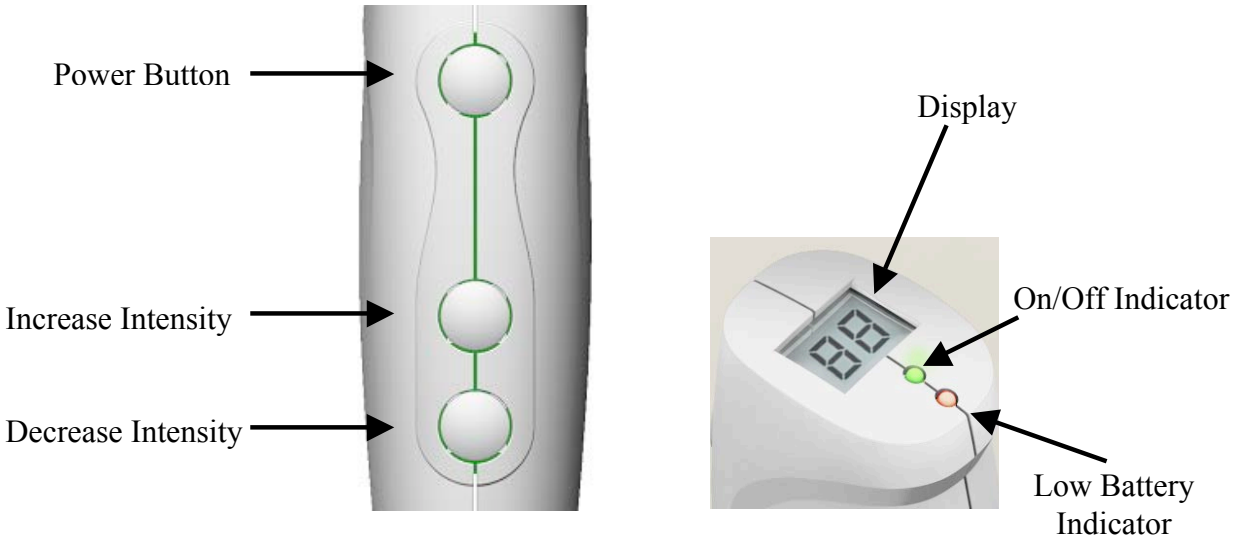


Changing the Beat Frequency

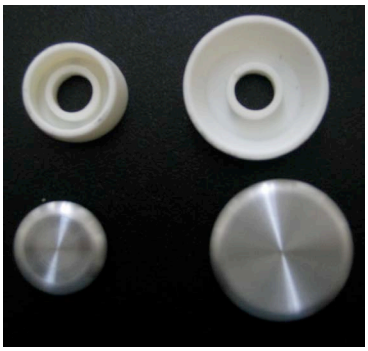
To vary the beat frequency, press and hold the power button for 10 seconds until the digits on the LCD flash. Change the beat frequency to the desired level using the increase/decrease buttons. To set the changed beat frequency, press the power button once.

Changing the Electrode Heads

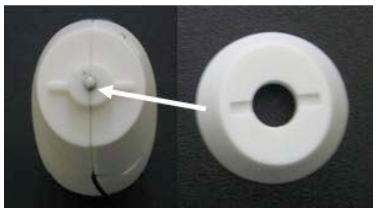
The MPD 1 includes two electrode sizes (1 inch, and 1.5 inch) each with corresponding plastic separators. The small separator matches up with for 1 inch head, large separator matches up with the 1.5 inch head (see Figure 3 below).

To interchange between these two sizes, first be sure the unit is powered off, or the battery is removed. Unscrew (counter-clockwise) the metal electrode head then remove plastic separator. Fit the corresponding plastic separator with desired metal electrode head grooves into the raised notches of the MPD 1 unit ensuring the separator is flush with the unit (see Figure 4 below). Screw in new electrode head until hand tight (see Figure 5 below).

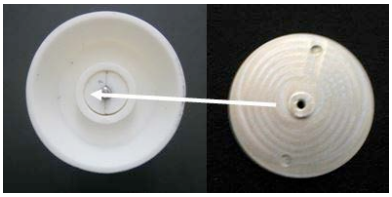
The unit will be inoperable without one of the electrode heads in place.



Electrode heads with corresponding plastic separators



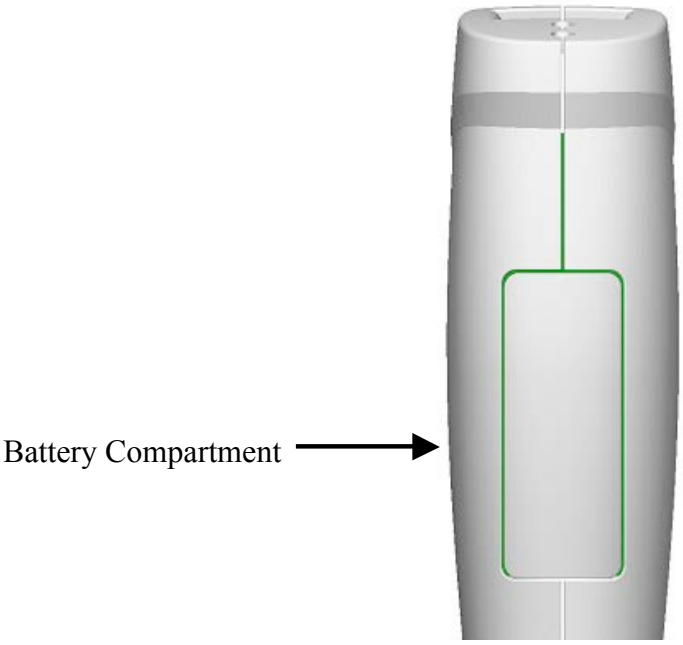
Plastic separator



Electrode head attachment

Battery

The MPD 1 uses a standard 9 volt battery. When the red low battery indicator is illuminated the battery must be replaced with a new 9 volt battery. Once the low battery indicator is lit, the device will not function until the battery is replaced. The battery compartment is located in the back of the MPD 1 (see Figure 2). Remove the door behind the MPD 1 and replace the 9 volt battery. EPGL Medical recommends removing the 9 volt battery from the device if not being used for two or more weeks.



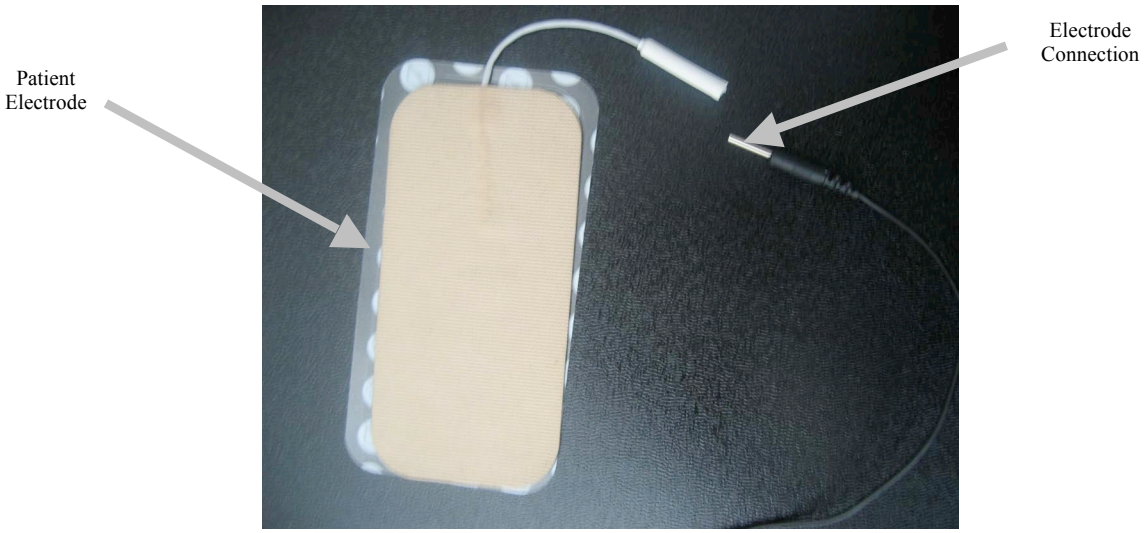
Patient Electrode Storage and Maintenance

IMPORTANT: Adhesive properties of the provided patient electrodes may be affected by ambient or patient skin conditions. While out of the package, extreme variations in humidity levels may affect the adhesive properties of these electrodes.

To increase the adhesive properties of the patient electrodes, add a few drops of water on the surface of the electrode and spread evenly. Allow two minutes for an increase in adhesiveness. If the electrode does not properly adhere to the skin following the addition of water discard and use a new electrode.

NOTE: EPGL Medical recommends the use of patient electrodes provided by EPGL Medical for use with the MPD 1 to ensure safety and efficacy of the treatment.

CAUTION: If patient electrode is damaged or appears worn discard and use new electrode.



Patient Electrode & Connector

Stimulation Site Preparation

1. DO NOT INCREASE INTENSITY UNTIL THE FOLLOWING PROCEDURE HAS BEEN PERFORMED. USE NEW PATIENT ELECTRODES FOR EACH PATIENT.
2. Clean the area(s) of the skin to be treated with soap and water or an alcohol wipe.
3. Excessive hair may be trimmed, but shaving immediately before electrode placement is not recommended.
4. Examine the patient electrode for damage. If the electrode is damaged, discard and use new electrode.
5. Ensure that the patient electrode is securely attached to the lead wire.
6. Avoid placing the patient electrode over broken skin, scars, discolored or inflamed areas, or any unusual areas of the skin.
7. Apply and spread gel over treatment area prior to making contact between the metal head and skin.

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8. Turn on unit and increase intensity until desired level is reached. Intensity may be increased at a higher rate by pressing and holding the increase/decrease button.
9. After treatment is complete, remove metal head from skin contact, turn unit off, then remove patient electrode.
10. Discard patient electrode and wipe treatment area with a dry towel to remove residual gel.
11. Clean metal head with alcohol wipe and store MPD 1 in the provided case.

Usage Duration

Usage duration should be limited to 15 minutes per session with a maximum of 4 sessions per day (or 60 minutes).

Indications for Use

The MPD 1 is indicated for the use with the following conditions:

1. Deep Stimulation of Muscle Trigger Points
2. Relaxation of muscle spasms.
3. Muscle re-education.
4. Maintaining or increasing range of motion.

Contraindications, Warnings, and Precautions

CAUTION: Federal law restricts this device to sale, distribution, and use by or on the order of a physician or any other practitioner licensed by the law of the state in which said person practices.

Contraindications

The device should not be used in the following areas:

1. On persons with suspected or diagnosed epilepsy. (seizure may occur)
2. Over the neck (carotid sinus), jaw, or mouth region (severe spasm of the laryngeal and pharangeal muscles may occur).
3. Over or around the eye area.
4. Trancerebrally.
5. On persons who are pregnant.
6. On persons who have known or suspected malignant lesions including cancer patients.
7. On persons who have implanted electrical devices such as a cardiac pacemaker or dorsal column stimulator.

Warnings

1. Electrical stimulation should not be used in electrically sensitive areas.
2. Electrical stimulation should not be used over open wounds, bruised, tender, swollen, inflamed, or infected areas of skin.
3. Precaution should be taken when stimulation is used on persons with suspected heart problems.
4. MPD 1 should not be used simultaneously with other devices or equipment.

5. Transthoracic application of electrical stimulation introduces electrical current into the heart and may cause arrhythmias.
6. MPD 1 should be kept out of reach of children.
7. Device is to be used only under supervision of a physician, physical therapist, physiatrist, pain management specialist, or chiropractor.
8. Isolated cases of skin irritation may occur at the site of electrode placement following long-term application.
9. Extra caution should be observed when using MPD 1 following recent acute traumas, fractures or corrective surgeries as muscle contractions may disrupt the healing process.
10. Do not use in close proximity to shortwave therapy equipment.
11. MPD 1 should not be applied over or near bone growth centers until bone growth is complete.
12. MPD 1 should not be applied over the vertebral column following laminectomy.
13. Output current density is related to electrode size. EPGL Inc. recommends the use of the provided electrodes with the MPD 1 device. If any additional questions arise, please contact EPGL Medical..

Precautions

Precautions should be taken when using the MPD 1 in the presence of one or more of the following conditions:

1. When using the device at current outputs above 40mA, extra caution should be observed to avoid skin burns by using adequate conductive medium (e.g. conductive gel) and by frequently alternating electrode placement.
2. Over the menstruating uterus.
3. When sensory damage is present by a loss of normal skin sensation.

Adverse Reactions

Adverse reactions to electrical stimulation are usually limited to sensations of discomfort. Excessive stimulation may cause spasms or soreness. Treatment and muscle stimulation should not exceed the patient's comfortable tolerance. Skin irritation and burns have been reported with the use of muscle stimulators. If any skin irritation or burns occur immediately end treatment

MPD 1 Specifications

Carrier Frequency:	2500Hz
Beat Frequency:	5 – 200Hz (default: 150Hz)
Duty Cycle:	50%
Intensity:	0 – 50mA
Waveform, shape:	Biphasic, Sinusoidal
Dimensions:	2"W x6.5"H x 1.55"D
Weight:	1/3 lbs (without battery)
	1/2 lbs (with battery)
Power Input:	9 volt DC

Calibration

EPGL Medical recommends the MPD 1 be periodically returned to EPGL for service and calibration. It is recommended the unit be calibrated in the field every 1 year or when major components are changed. Please call (877)-287-6175 to request a Return Number and directions on how and where to return the device.

Trouble-Shooting

Error Messages

The MPD 1 is equipped with circuitry which continuously performs self-diagnostic tests to assure the unit is working properly. Error messages will be displayed on the LCD if failure of any test component is positive. Error messages include:

Error Message	Meaning	Trouble-Shooting
LO	Low Battery	Replace Battery
E1	Power On Self Test	Remove and re-insert battery
E2	ROM Operational Error	Remove and re-insert battery

For any questions, please contact EPGL at (877)-287-6175.

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